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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DANGUOLE SPAKEVICIUS and HATICE OZSOY

Appeal 2016-004192
Application 13/318,591[1]
Technology Center 1600

Before JEFFREY N. FREDMAN, TIMOTHY G. MAJORS, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of treating or reducing inflammation. The Examiner rejected claims 78 and 82 on appeal under 35 U.S.C. § 103(a) as obvious.

We reverse.

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[1] According to Appellants, the real party in interest is the Board of Regents, The University of Texas System. App. Br. 2.

STATEMENT OF THE CASE

Claims 78 and 82 are on appeal. Claim 78 is illustrative and reads as follows:

> 1. A method of treating or reducing inflammation in a subject in need thereof, said method comprising administering to said subject a composition comprising a construct in an amount effective to treat or reduce said inflammation, wherein said construct is selected from the group consisting of:
>
> (a) a volatile anesthetic dissolved in a solution, wherein said solution further comprises at least one extractive solvent in an amount effective to reduce volatility of said volatile anesthetic, and
>
> (b) a micro-droplet suspension comprising a sphere of a volatile anesthetic surrounded by a stabilizing layer of a phospholipid;
>
> wherein said administration is topical, mucosal, rectal, vaginal, or buccal; and wherein the at least one extractive solvent is selected from the group consisting of dimethyl sulfoxide (DMSO), dimethylformamide (DMF), dimethylacetamide (DMA), N-methyl-2-pyrrolidone (NMP), dimethylisosorbide, ethanol, propanol, PEG-400, PEG-300, diethylene glycol monoethyl ether, and isopropanol, and
>
> wherein said volatile anesthetic is selected from the group consisting of isoflurane, halothane, enflurane, sevoflurane, desflurane, methoxyflurane, and mixtures thereof.

App. Br. 13.

In response to a species election requirement, Appellants elected species construct "a)" (i.e. volatile anesthetic in a solution comprising an extractive solvent). Ans. 2. However, the Examiner mistakenly examined species "b)" (i.e., a micro-droplet suspension comprising a sphere of volatile anesthetic). *Id.* The Examiner informed Appellants of this mistake and provided the opportunity to reopen prosecution. *Id.* Appellants elected not to reopen prosecution and proceeded based on examination of species "b)".

Accordingly, for purposes of this appeal, we limit our consideration of the merits of the appealed rejection to species "b)". *See Ex parte Ohsaka,* 2 USPQ2d 1460, 1461 (BPAI 1987).

The Examiner rejected claims 78 and 82 under 35 U.S.C. § 103(a) as unpatentable over the combination of Haynes I[2] and Haynes II.[3]

ANALYSIS

The Examiner found that Haynes I disclosed micro-droplet suspensions comprising a volatile anesthetic surrounded by a stabilizing layer of phospholipid. Final Act. 3. The Examiner also found that Haynes I disclosed administration of the micro-droplet suspensions to treat inflammation. *Id.* at 3–4. While Haynes I discloses a "variety of suggested administration routes," the Examiner found that Haynes I did not disclose "topical, mucosal, rectal, vaginal, or buccal" administration. *Id.* at 4.

The Examiner found that Haynes II disclosed compositions incorporating crystalline, water-insoluble drugs in phospholipid micro-droplets and that the "most advantageous route of administration for the composition includes topical administration." *Id.*

Based on the combined disclosures of Haynes I and Haynes II, the Examiner concluded:

> it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method of treatment taught by Haynes [I] by administering the composition topically as taught by [Haynes II] because [Haynes II] teaches that in addition to injection, the composition of Haynes [I] and other types of phospholipid-coated constructs, which

[2] Haynes, US Patent No. 4,622,219, issued Nov. 11, 1986 ("Haynes I").
[3] Haynes, US Patent No. 5,091,188, issued Feb. 25, 1992 ("Haynes II").

> contain water-insoluble drugs (e.g., volatile anesthetics) [] may be administered topically and one of ordinary skill in the art could have selected topical administration from the finite preferred routes of administration to yield nothing more than predictable results.

Id. at 5.

Appellants argue, *inter alia,* that Haynes I "indicates that administration of a volatile anesthetic to the skin should be avoided, since volatile anesthetics are not absorbed well through the skin." App. Br. 4. Appellants further argue that Haynes II "relates only to pharmaceutical preparations containing microcrystals . . . [and] does not relate to the instantly claimed anesthetics, which would immediately be recognized by one of skill in the art to be liquid and volatile at room temperature, *i.e.,* non-crystalline." *Id.* Because Haynes I and Haynes II relate to different and unrelated classes of drugs, Appellants argue, "one skilled in the art would not have been motivated by Haynes II . . . to modify the teachings in Haynes I [so] as to arrive at the present invention." *Id.* at 6. We find that Appellants have the better position.

Haynes I does not teach the use of volatile anesthetics to treat inflammation. Rather Haynes I uses volatile general anesthetics as local anesthetics (Haynes I, col. 1, ll. 39–41) and as the "organic phase" of the microdroplet. *Id.* at col. 4, ll. 32–48. In finding that Haynes I taught treatment of inflammation, the Examiner relied on the disclosure in Haynes I that a variety of drug substances can be incorporated in the microdroplets formed by this process, including anti-inflammatory agents like phenylbutazone, acetaminophen and colchicine. Ans. 4 (citing Haynes I, col. 7, ll. 42–50). Since the organic phase of the microdroplet may include

volatile anesthetics (*Id.* at col. 4, ll. 42–48), a construct of Haynes I including an anti-inflammatory agent as the active pharmaceutical agent meets the claim requirement for a construct comprising a volatile anesthetic.

The Examiner used Haynes II as evidence that the volatile-anesthetic-containing composition of Haynes I could be administered topically. Ans. 8–9. The Examiner, however, does not identify any teaching in Haynes II that would have caused a skilled artisan to expect that a construct employing a volatile general anesthetic as the active ingredient could be administered topically to treat inflammation. Nor does the Examiner identify any teaching in Haynes II that would have caused the skilled artisan to expect the microdroplets of Haynes I, formulated to incorporate an anti-inflammatory agent as the active ingredient, could be administered topically *to treat inflammation.*

The Examiner contends that there is "a reasonable expectation of success to modify the composition construct of Haynes [I] for topical administration because [Haynes II] teaches that in addition to injection, the composition of Haynes [I] and other types of phospholipid-coated constructs, which contain water-insoluble drugs (e.g., volatile anesthetics) may be advantageously administered topically." Ans. 9. But the teaching of Haynes II relates to the phospholipid construct, not the drug contained within the construct. The teaching that crystalline drugs can be coated with phospholipids (as taught by Haynes II) does not provide sufficient reason for the skilled artisan to expect that any phospholipid coated drug can be administered topically *to treat inflammation.*

The Examiner notes that Example 14 of Haynes II discloses a microdroplet including methoxyflurane – a volatile anesthetic. Ans. 8.

There is, however, no indication that the composition of Example 14 was administered to treat inflammation. Indeed, the methoxyflurane in the example was used as a solvent to solubilize the active, a muscle relaxant. Haynes II, col. 31, l. 62 – col. 32, l. 4 (Example 14).

Accordingly, we reverse the Examiner's decision to reject claims 78 and 82 under 35 U.S.C. § 103(a) as obvious over the combination of Haynes I and Haynes II.

SUMMARY

For the reasons provided herein the Examiner's decision to reject claims 78 and 82 under 35 U.S.C. § 103(a) as unpatentable over the combination of Haynes I and Haynes II is reversed.

REVERSED